K061857
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510(k) Summary
Model Multi-Flo IC-1545-KT/-F Intermittent Circulator AUG 0 1 2006
510(k) Number _____

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1. APPLICANT'S INFORMATION:
   Ron Motherwell
   Executive Vice President
   PH: **201** 939-0716
   FX: **201** 939-4503
   Internet: http://www.biocompression.com
   Medical Establishment
   Registration No.: 2424387

2. SUBMITTER'S INFORMATION
   James Jochen Rogers
   General Manager
   Coastal Consulting Group, Ltd.
   P.O. Box 470218
   Broadview Heights, OH 44141
   PH/FX: **440** 546.4936
   Mobile: **724** 713.2298
   E-mail: coastalcg@earthlink.net
   Internet: http://www.coastalcg.com

3. Date: June 1, 2006

4. DEVICE INFORMATION
   DEVICE NAME: Model Multi-Flo IC-1545-KT/-F Intermittent Circulator
   Classification Panel: Cardiovascular and Respiratory Devices
   Classification Number: 870.5800
   Product Nomenclature: Compressible Limb Sleeve
   Product Code(s): JOW
   Trade/Proprietary Name: Model Multi-Flo IC-1545-KT/-F Intermittent Circulator
   Common Name: Model Multi-Flo IC-1545-KT/-F Intermittent Circulator
   510(k) Submission Type: Traditional
   Request for Confidentiality under 21CFR §807.95: NO

5. DEVICE CLASSIFICATION:
   Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular Devices.

6. PREDICATE DEVICE(s):
   - K932900 Aircast Inc. Venaflow System
   - K965153 Huntleigh Healthcare FP5000
   - K881632 Huntleigh Healthcare Flowtron DVT AC500
   - K043423 Model SC-3008 Sequential Circulator

7. DEVICE DESCRIPTION:

The device is available in two models (-KT and –F) and is intended for use to help prevent deep vein thrombosis (DVT) by increasing venous blood flow (prophylaxis). One DVT prophylaxis model is intended for use on the calves or calves and thighs, while the second model is intended for use on the feet. Connector variations prevent interchangeability of garments between the models.

The device for consists of a pump, inflatable garments, and interconnection tubing. The pump is manual (e.g., inflate/deflate cycle times remain constant, and pressure is pre-set at the factory), and contains a compressor capable of a maximum pressure of 150mmHg. A calibrated dial gauge displays pressure in the range of 0-125mmHg. Should the attending physician require a higher or lower pressure from the preset value, an over-ride adjustment control is available. An integrated wire bail is provided to conveniently attach the device to the patient bedrails.

For DVT prophylaxis, the device is attached via interconnect tubing to sleeves or garments containing discrete, interconnected, and segmented inflatable chambers applied externally and bilaterally over the lower extremities. The pump provides intermittent, rapid impulse pressurization to the chambers. The garment design achieves sequentially inflation of interconnected chambers distal to proximal, and a "bleeding" mechanism ensures that distal chambers are inflated to a greater pressure than the proximal ones. The last chamber bleeds off pressure to the ambient atmosphere. An external manual adjustment available for pressure override, and an alarm is provided for low/no pressure. When the bilateral DVT prophylaxis garments are inflated, they compress the veins in the calf, expelling blood from the leg, overcoming blood stasis and promoting circulation.

Garments are available in three anatomical configurations, are supplied non-sterile, and are intended for single patient use.

The device is intended for hospital and home use.

8. INDICATIONS FOR USE:
When used with GI-3045-T Knee/Thigh or GI-3045-K Knee garments:
- Intended for prophylaxis of deep vein thrombosis

When used with GI-3045-F Foot garments:
- Intended for prophylaxis of deep vein thrombosis
- Enhancement of venous and arterial circulation
- Prevention of venous stasis ulcers
- Assist in healing of cutaneous ulcers
- Reduction of acute or chronic edema
- Reduction of lower limb pain due to surgery or trauma
- Reduction of compartmental pressures

9. TECHNOLOGICAL CHARACTERISTICS:
The manufacturer believes that the technological characteristics of the Model Multi-Flo IC-1545-KT/-F Intermittent Circulator are substantially similar to those of the predicate devices.

10. PERFORMANCE DATA:
Performance testing was performed and assures that the product meets its specifications.

Bench testing was performed, comparing the inflation cycle profiles of the product to the predicate devices. The results of the testing demonstrate similar risetimes (time required to reach pressure), cycle times (total inflated and deflated times within a cycle), and inflation pressures.

11. STATEMENT OF SUBSTANTIAL EQUIVALENCE:
Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices in terms of features, functionality, and bench comparisonal testing, the manufacturer believes that the Multi-Flo IC-1545-KT/-F Intermittent Circulator is substantially equivalent to the predicate devices, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

Bio Compression System, Inc.
c/o Mr. Ned Devine
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K061857
Trade Name: Model Multi-Flo IC-1545-KT/-F Intermittent Circulator
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: June 20, 2006
Received: July 21, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061857

Device Name: Model Multi-Flo IC-1545-KT/-F Intermittent Circulator

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- Reduction of compartmental pressures

The device is intended for hospital and home use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Hudson

(Division Sign-Off)
Division of Cardiovascular Devices

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